

EXHIBIT D

MICHAEL R. REED
UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re Bair Hugger Forced

Air Warming Products

Liability Litigation,

MDL No. 14-2666 (JNE/FLN)

VIDEOTAPED DEPOSITION OF

MICHAEL R. REED

London, United Kingdom

Taken December 4th, 2016

By Rose Kay

Job No. 115951

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THE EXAMINER: At the top of --

MR. GORDON: At the beginning of the text on page --

MR. ASSAAD: Oh, thank you.

THE EXAMINER: Sorry, what was the question arising out of that?

BY MR. GORDON:

Q. What does that refer to?

A. Well, that's essentially the data that we collect on patients as they come in and have a joint replacement.

Q. Did you just start collecting that data on 1st July, 2008?

A. I think that's probably about right, yes. That's when we went to full-time surveillance. We didn't have a surveillance team. We had part-time surveillance. So in England, there's the -- the NHS law is that you have to submit the one quarter every year, one operation infection rates. And we moved to full-time surveillance in that time. So we had a complete handle on infection rates from that point.

Q. And at the end of that 2.5-year period, did you stop collecting data?

A. No. We still collect data.

Q. The 2.5-year period is the -- would be the time period of the McGovern paper, right? That's -- it's just

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a finding that what -- the book-ends of the study?

A. Yes.

Q. Okay.

So when you -- at the start date of 1st July, 2008, patients were being warmed with the Bair Hugger; is that correct?

A. Yes.

Q. And at some point, you transitioned over from warming patients with the Bair Hugger to warming them with the Hot Dog; is that correct?

A. Yes.

Q. And at some point, you were fully transitioned and only had -- were only using the Hot Dog?

A. Yes.

Q. Is that correct?

A. Yes.

Q. So there were really three periods in that 2.5 years. The first period being Bair Hugger only; the second period being transition; and the third period being Hot Dog; is that correct?

A. Yes.

Q. What was the period of Hot Dog only use?

A. So that's in the paper. It's from -- it was something like June till -- until the end of December.

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Q. Of ...?

THE EXAMINER: Where is this?

A. So this is page 546. And it's the chart which has been written on.

THE EXAMINER: Oh, I see.

BY MR. GORDON:

Q. So June to December 2010?

A. Yes, I think it's June.

MS. ZIMMERMAN: What page was this?

MR. HOLL-ALLEN: 546. This is the table ...

BY MR. GORDON:

Q. Would that be seven months?

A. It feels about right. Six or seven months.

MR. ASSAAD: There's markings on this page. Did you mark ...

THE EXAMINER: I am a bit confused to where the proper lines are, in the light of all these ...

So you used the Bair Hugger from July 2008 to March -- February/March 2010?

A. No. So the -- what's the best way to explain this chart? So if you can try and ignore the scribbles.

THE EXAMINER: Yes, I am trying to.

MR. HOLL-ALLEN: Sir, I am sorry to interrupt. In the plaintiffs' file, there is a clean copy of the same

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document.

THE EXAMINER: Thank you. I don't have the plaintiffs' file.

MR. ASSAAD: And I would prefer to use that, because it seems that this document was used during the Albrecht deposition that was taken in October(?) 2016 and I had to have -- these markings could influence the witness's testimony today. So I would rather have a clean copy.

THE EXAMINER: That is another reason. The principal reason is that it's virtually impossible to understand, with all these markings on it.

MR. HOLL-ALLEN: Would you like to use my copy, sir?

THE EXAMINER: No, it is more important that you have it than I do.

BY MR. GORDON:

Q. Well, let's skip that chart. If you go back to page 543 --

MR. ASSAAD: Are you moving on to the ...

MR. GORDON: No, that was the ...

THE EXAMINER: Which one of these is ...?

A. I think --

BY MR. GORDON:

Q. Under "Joint infection data", there is a reference to: a transition of warming -- forced air warming to

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THE EXAMINER: Okay.

A. I mean, there is an enormous amount of operations that fall into those groups. You are probably right, but I don't -- I think a coder wouldn't rely on that to say whether it was trauma or not.

BY MR. GORDON:

Q. When you initially saw a printout of data for use in the McGovern study, did you limit it to non-trauma, hip and knee surgeries?

MR. ASSAAD: Objection, misstates the prior testimony. Lack of foundation. He never stated he saw a printout.

THE EXAMINER: You can answer.

A. So normally, the patients you get on here are elective. So there will be some that come on, that are not elective, and then they will be removed by the surveillance team and put -- not actually removed, but put into a different category of joint replacement.

BY MR. GORDON:

Q. When you compiled the data for the McGovern study, did you in any way try to separate the trauma and the non-trauma patients?

MR. ASSAAD: Objection, misstates the prior testimony.

THE EXAMINER: You may answer.

A. I mean, we definitely attempted to do that, because this

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database is meant to be just planned cases, just elective cases.

BY MR. GORDON:

Q. Okay. And by --

A. But we do know that other ones get in through coding and then they will be taken out in the sort of data cleaning process.

Q. By this database, you mean the 788 through 1050 -- 1081?

A. So you know, before we would publish, if you like, on infection rates, then we would go through it, we would check every case is as -- you know, every case, whether the infection is trauma or not. You might by chance end up pulling one out, you might not. I am not aware whether we did with this study.

Q. Okay. The data here, on 788 through 1081, as Mr. Dyer pointed out, began on 1st October, 2007. What was your reasoning for commencing the Bair Hugger only period on 1st July, 2008?

A. So my recollection is that we got a full-time surveillance team at that point. So as I said, previously in the U.K. you only have to do a quarter. Actually, you can choose which operation you do. So you might not have full-time surveillance prior to that.

THE EXAMINER: So one operation, one quartile, per annum?

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A. Correct. That's the national standard. But we have moved to doing every operation full-time; and that's why we have got that reliable data. So there would be big gaps in the period. If you looked at 2006, you might only have a quarter of the year populated, which would be very unreliable data.

THE EXAMINER: Yes.

BY MR. GORDON:

Q. So I really want to drill down on the timing; and that is critical. I am going to ask you to take a look at volume 2, pages 487 through 490.

A. Okay.

Q. Have you seen this before?

A. I saw it yesterday.

Q. Is that the first time you saw it?

A. I'm not sure.

MR. ASSAAD: I am going to object for lack of foundation for any questions being asked, if he hasn't established foundation. He has written this document -- the authorship of this document --

THE EXAMINER: You have made your objection. Keep objections short.

MR. ASSAAD: Well, I need to put all the objections for the U.S. court.

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THE EXAMINER: I know.

MR. GORDON: They are all preserved.

THE EXAMINER: I am familiar with how U.S. attorneys --

MR. ASSAAD: They are --

MR. GORDON: The only objection is: waives form or foundation.

MR. ASSAAD: I am only doing it for trial --

BY MR. GORDON:

Q. Do you know who Julie Gillson is?

A. Yes. Julie Gillson was one of our matrons.

Q. What is a matron?

A. So it is a senior nurse, essentially.

Q. Was she one of the SSI surveillance nurses?

A. No. So Julie is a matron, so the senior nurse within surgery, if you like. Gail Lowdon leads the surgical site infection surveillance team.

Q. And if you look at the front page of this document. At page 71, the very last paragraph, it says during --

THE EXAMINER: Where are you?

BY MR. GORDON:

Q. Page 71. Oh, I am sorry.

THE EXAMINER: 487.

MR. GORDON: 487, thank you. Page 487, the last full paragraph on the page:

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"During the last two quarters of 2008/2009, Northumbria Healthcare NHS Foundation Trust was reporting SSI rates in the combined total of surgeries in the THR/TKR and repair neck of femur between 3.5 percent and 5.7 percent and was regularly receiving letters from the HPA informing the trust of its high outlier status for SSI."

First of all, did I read that correctly?

A. Yes.

MR. ASSAAD: Objection. Move to strike for hearsay.

BY MR. GORDON:

Q. Did --

THE EXAMINER: (Overspeaking.) ... moving on to a question --

MR. ASSAAD: He can't read evidence in, without establishing a foundation. I am saying this is hearsay. He is reading someone else's words into the record. He is basically advocating this point. Objection for hearsay.

BY MR. GORDON:

Q. Do you recall there being a period of time when the Northumbria Healthcare Trust was getting letters from the HPA about SSI rates?

A. Yes.

Q. And what were those -- first of all, what is the HPA?

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A. So the HPA is the Health Protection Agency and they are the group that collate the national database, based on people collecting it locally. So Gail Lowdon who leads our surgical site infection surveillance team, a member of her team will be uploading that information nationally, if you like, to the Health Protection Agency.

The issue with that is that not every trust puts in the data as we have established; and the infection rates that they quote are very low and, in fact, they have -- I mean, the government advisers on infection have publicly written to say that their quotes -- they quote very low infection rates, unrealistically low, because the surveillance system is poor in many trusts?

THE EXAMINER: Do you have a recollection of these letters being received?

A. Yes.

THE EXAMINER: Okay.

BY MR. GORDON:

Q. And what did Northumbria do in response to those letters?

A. So I mean, we have done lots of things, as I think has become clear. We have made loads of changes over a period, a sustained period, to try and reduce the

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infection rates.

Q. Was there any type of a committee or a working group formed?

A. Yes. So there was a surgical site infection prevention committee, which I chair.

Q. And when was that formed?

A. It may actually even be on here. About 2008, maybe even 2007. That sort of timescale.

Q. And that's your independent recollection?

A. Yes.

Q. So the reason I say that is that on page 548, it says that the multiple -- a multi-disciplinary team formed the trust SSI group and the first meeting took place in December 2008.

A. There you go then.

Q. Well, if you --

THE EXAMINER: What is the --

BY MR. GORDON:

Q. If your recollection is different than what is here --

A. Yes, I think that feels right and she would know. What I would say is that we may have been doing stuff before that, before we did a formal meeting, but it would not have been long before that.

Q. And there is a reference in the next paragraph to:

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"The first action point of this meeting was to place a successful bid to appoint two full-time SSI nurses on a 12-month secondment."

MR. ASSAAD: Objection, hearsay.

BY MR. GORDON:

Q. And my question is: was there -- were there full-time SSI nurses prior to whenever this multi-disciplinary group first met?

A. Yes, so the -- the surveillance was done -- I mean, we should probably go back one step.

So we were named in the paper, based on the 2007 data, as having a high infection rate. And after that, we went to full-time surveillance, some time probably in early 2008, but we didn't have the business case and people -- and people formally appointed to those rules. They were being done, I think, by infection control, rather than by a surveillance team. Same methodology.

MR. ASSAAD: I am going to object again to those line of questions. It is not part of the subject matter of the sealed order. It has nothing to do with the studies that he has been performing, that it has been limited to -- by the Senior Master.

THE EXAMINER: He is still in the --

MR. ASSAAD: I mean, we -- well, it really isn't. It is

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"This study does not establish a causal basis for this association. Although the demographics were similar between the patient groups in terms of risk factors for infection, the data are observational and may be confounded by other infection control measures instituted by the hospital. For example ..."

THE EXAMINER: Where are we?

MR. GORDON: Page 546.

THE EXAMINER: Yes, but where?

BY MR. GORDON:

Q. On the left hand side, the first full paragraph that begins:

"This study does not establish a causal basis ..."

But you say:

"For example, changes were made to the antibiotic and thromboprophylaxis protocols used during the study, although no infection control changes were made after February 2010."

And my -- I am emphasizing the words "For example". You've got thromboprophylaxis and antibiotics specified in here.

But my question is: are there -- did I miss it or are there any other places within there, where you actually -- within the McGovern paper, where you talk

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about what other changes had occurred or when?

A. So we did -- we obviously listed that there were changes, so we chose two specific ones, because they are the ones really with the evidence base or the concern around them.

So to turn that on its head, if I was to say, you know: we changed the color of theater blues in the article here on infection, they would say: well, where is the evidence for that, that influence? And you wouldn't find a reference for that either.

So a lot of the things we have done are on the basis of common sense, rather than evidence that it will help infection. I would accept that.

Q. Did you change the dressings?

A. That's -- at one point we changed the dressings, yes.

Q. From what to what?

A. So I am struggling to think if we had a policy before we changed, in terms of -- I think it was probably certain preference. But after we changed, it was to something called Aquacel Surgical.

Q. Is that the same thing as Jubilee?

A. Jubilee, yes. Jubilee is --

Q. The hospital?

A. The hospital that invented it. The Golden Jubilee.

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Q. Was there any evidence to support switching to the Jubilee dressing?

A. So they had evidence.

THE EXAMINER: "They" being?

A. The Golden Jubilee had done a small trial on it.

BY MR. GORDON:

Q. The hospital in Glasgow?

A. Yes.

Q. What did their trial demonstrate?

A. So they looked at a variety of outcome measures, but the ones I remember were blister rates. So you can sometimes get blistering around a wound. And they were reduced with that dressing, and infection rates were reduced. I can't remember whether that was superficial and deep or whether it was just deep. But there was a -- there was an effect.

Q. And when did you switch to the Jubilee dressing?

A. It's probably on the timeline, I think.

Would you care to point it out, to speed me up?

There is a lot on here.

Q. If I am reading correctly, it is the October 2009.

THE EXAMINER: Right at the bottom left hand side, at the bottom, in the yellow box.

A. Okay. So ...

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THE EXAMINER: Well, that's audit.

A. Yes, it's audit. I am not quite sure what that means.

It may well have changed well ahead of that. There is another wound dressing audit you see underway, I think, at the beginning of 2008.

THE EXAMINER: I see, yes.

A. So I couldn't say with any certainty when we changed, but it was a pretty early change, I think, that we made.

BY MR. GORDON:

Q. Would it have been before or after the audit?

A. Well --

THE EXAMINER: You can't audit something you are not using.

A. No, so I mean, I think -- I am struggling to know whether in quarter 1 2009 we introduced it or whether it was before that. I don't know.

BY MR. GORDON:

Q. Okay. But it was before --

A. It probably is written somewhere in your documents.

Q. It was before the switch to Hot Dog; right?

A. I mean, my recollection is that it was, but I couldn't say with any certainty.

Q. Did there come a point in time when, at Wansbeck, you started screening hip and knee patients for methicillin resistant staphylococcus aureus, MRSA?

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A. No. We have always done that, but I think you are alluding to sensitive staph aureus.

Q. That was my next question. So you have always done the first screening?

A. Yes, I can't remember when we didn't.

Q. But my next question -- yes. So did there come a time when you -- was there a time when you had not been screening for methicillin susceptible staphylococcus aureus, and you started screening for that?

A. So that was in early 2010, I think we started screening for that.

Q. And was it just screening, or did somebody who had -- did you take some action?

A. So we would decolonize patients to -- essentially what you are trying to do is to reduce the load of this particular bug in someone's nose or on their hands or whatever.

Q. So some of the Bair Hugger only patients would have not had the benefit of MSSA screening; some of them would have? Either way -- did you say February 2010?

A. I think it was January, but ...

Q. Okay. So at the very end of the Bair Hugger only period?

A. Yes.

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Q. So if you were the Bair Hugger -- some of the Bair Hugger patients at the very end would have had MRSA screening and all of the Hot Dog only patients had the benefit of MSSA screening?

A. That is due. But what I would say is that there is no evidence that it reduces infection rates in this group; certainly at this point. That may not be the case now, six years down the line. But yes, it was introduced with that intention.

Q. Did there come a point in time when you instituted pre-warming of patients for hip and knee ...?

A. Yes.

Q. When was that?

A. It will probably be on the timeline.

THE EXAMINER: What does it mean?

A. So essentially, if you warm someone up before their operation, then they are less likely to get cold during their operation. If you are less likely to get cold during the operation, then it reduces your complications of bleeding, heart attacks and perhaps infection.

BY MR. GORDON:

Q. Well, had you seen any studies before you implemented the pre-warming, to address that specific issue; does it have any impact on infection?

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A. So it does have an impact on infection. But I think what's less certain is whether it has an impact on infection if you warm them in theater as well. So isolated pre-warming has an impact on infection.

In fact, David Leaper, who you are going to meet, published that in a very good large study. But my recollection is that those patients weren't warmed during surgery.

Q. Are you talking about the Melling paper from 2001?

A. Yes.

Q. Was there a study closer in time, so when you switched to pre-warming that you had seen ...?

A. So I have certainly seen a study that shows that if you pre-warm people, they are less likely to get cold, so that's like a proxy. So I have certainly had that in some of my presentations.

Q. Have you ever indicated that in your presentations, that you read the New England Journal and found some article about a significant reduction in infection rates by adding pre-warming, and then you decided to do that as part of your routine procedures?

MR. ASSAAD: Objection, leading.

A. That was David Leaper; David Leaper's study, I think. I think that was in the Lancet, actually, David Leaper's

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study. Is pre-warming in the New England Journal of Medicine? I am not aware of that.

BY MR. GORDON:

Q. Okay. I am not going to take time going into too many more ...

A. There is now good evidence evolving, but it is coming into practice as a definite now, compulsory. This is six years down the line.

Q. When did you start pre-warming patients?

A. It is probably on the timeline. Can you point that out for me?

Q. I think it is probably the second quarter of 2010.

A. Okay. It is likely to be correct if it is on here.

THE EXAMINER: Yes, it is part of the entry in the yellow box.

BY MR. GORDON:

Q. The yellow box up on the top bit.

A. Yes, I am not sure that the Lancet study -- and I am genuinely not sure. But I think that is not based on the people who are warmed during the operation as well. I think in David's study, they were only pre-warmed.

Q. The 2001 Melling --

A. Yes.

THE EXAMINER: So in your hospital, as from June 2010 they

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A. Rarely, but to get to that point, there is a huge number of surgeries normally as well.

Q. And potentially it could cause death?

A. Yes. Well, it does cause death. I mean, there is a definite association with mortality. It reduces your life span.

Q. Do you consider yourself an expert in peri-prosthetic joint infections?

A. Well, in, you know, the view that I have been invited to the international consensus perhaps, and I do speak frequently on it at meetings. I spoke yesterday in Manchester on it. So yes, I speak quite frequently on it.

THE EXAMINER: And my understanding is that it is not that there is a significant percentage or proportion of infections in this surgery. It is because of the severity of the cost to --

A. Exactly. So it is the severity of the complication which is just game changing for most patients. It is a terrible, terrible complication.

BY MR. ASSAAD:

Q. And do you consider yourself an expert with respect to the causation of peri-prosthetic joint infections?

A. I think "expert" is maybe for someone else to judge, but

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I do know a lot about it and I have spent a lot of time researching it.

MR. ASSAAD: We need to go off the record, because of the change of CD.

THE VIDEOGRAPHER: This is the end of tape number 2 in the deposition of Michael Reed. Going off the record at 4:44.

(4:44 pm)

(Break taken.)

(4:49 pm)

THE VIDEOGRAPHER: This is the beginning of tape number 3 in the deposition of Michael Reed. Going on the record at 4:48.

BY MR. ASSAAD:

Q. Mr. Reed, we can agree that you need a bacteria to cause a peri-prosthetic joint infection; correct?

A. Yes.

Q. And we can agree that because of the implant, you need very few bacteria to cause a peri-prosthetic joint infection; correct?

A. Correct.

Q. Contrary to a wound infection, where you might need millions; correct?

A. So if you don't have an implant in situ, then you can

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have many, many more bacteria on the wound without getting an infection. So yes, it is much more important when you have got an implant.

Q. So an implant is highly susceptible to a bacteria and the cause of a peri-prosthetic joint infection mainly because of biofilm; correct?

A. Yes, so biofilm is a slime that the bacteria produce that protect it from antibiotics and other mechanisms the body might have to rid the infection. So yes, it is very -- it is driven by biofilm, we think, the difficulties in getting rid of the infection.

Q. And you would agree with me that as a result -- strike that.

You would agree with me that most, if not all of the peri-prosthetic joint infections occur when bacteria gets to the implant during the perioperative period; correct?

A. I am not sure we know that. That's -- but that is sort of an accepted philosophy. But I don't think we know that for sure, in actual fact. But that is the dogma.

THE EXAMINER: You referred to the peri ...?

BY MR. ASSAAD:

Q. Peri, during the surgery.

THE EXAMINER: I see, during the operation.

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BY MR. ASSAAD:

Q. When you say that is the accepted philosophy, that is the main consensus among most orthopaedic surgeons; correct?

A. Yes.

Q. And because of the biofilm, it is very difficult to treat these peri-prosthetic joint infections through medication; correct, such as antibiotics?

A. Yes. Essentially you can't get rid of an infection with antibiotics alone.

Q. Because there is no vascularity to the joint?

A. Yes, because -- because bacteria and biofilm become very protected by the slime, and so you need about a thousand times the dose of the antibiotic for it to work, and you can't deliver that much antibiotic to the patient.

Q. Have you heard of the term "chain of infection"?

A. Can you -- can you rephrase that?

Q. Yes, I can actually. Basically, for an infection to occur, you have to have an infectious agent, a reservoir, a portal of exit, a mode of transportation, a portal of entry and a susceptible host. Have you heard that described before?

A. Yes.

Q. And for example, so with respect to the infectious